IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 06-222 JJF **PUBLIC VERSION**

DEFENDANT IMPAX LABORATORIES, INC.'S
BRIEF IN SUPPORT OF MOTION TO COMPEL
DEPOSITION PURSUANT TO FED. R. CIV. P. 30(B)(6)

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I. INTRODUCTION

As is typical of Hatch-Waxman patent litigation between large pharmaceutical companies and generic drug manufacturers, the stakes here are very high. In this case, revenue of over $6.8 million a day depends on the outcome.[1] Accordingly, Wyeth is doing everything in its power to delay a generic entrant from entering the market with a lower-cost alternative by making this litigation as complicated, expensive and time-consuming as possible. Their job is to obfuscate and our job is to narrow the issues to those that really matter. This case involves millions of documents and literally potentially hundreds of individuals who might have relevant knowledge regarding the evolution of this time-release technology, the patents and the circumstances regarding this action and the inequitable conduct, spanning a period of over 15 years. In an attempt to break through the log jam of the millions of documents and hundreds of potential deponents so that this case can be manageably tried, and more importantly *to simplify the issues for trial*, Impax Laboratories, Inc. ("Impax") served a Rule 30(b)(6) deposition notice, listing eight general topics that would force Wyeth to designate the proper witnesses so as to probe factual allegations made by Wyeth, as well as several potential defenses without wasting depositions.

As Wright & Miller stated, this is precisely why Rule 30(b)(6) was enacted:

Rule 30(b)(6) was designed to reduce difficulties that occurred before

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[1] Wyeth's U.S. sales revenue for Effexor XR was over $2 billion in 2005 and about $2.5 billion in 2006.

A decision in favor of Impax is expected to lead to a launch of a generic extended release formulation of venlafaxine by Teva Pharmaceuticals, who was the first generic drug manufacturer to file a Paragraph IV Certification to the FDA followed by other generics including Impax. In prior litigation with Wyeth involving the same patents asserted here, Teva obtained a claim construction of the patents-in-suit limiting the claimed invention to an extended release formulation containing microcrystalline cellulose ("MCC"). However, Teva settled with Wyeth on the eve of trial when Wyeth enticed Teva with a license to sell its generic immediate release product about two years before the expiration of another Wyeth patent covering the venlafaxine compound.

> 1970 in designating the proper corporate officer or agent and to *avoid the possibility that several officers and managing agents might be deposed in turn, with each disclaiming personal knowledge of facts that are clearly known to persons within the organization and thus to the organization itself.*
>
> Prior to the 1970 amendment the courts had generally held that the party seeking a deposition could not put the burden on a corporation to decide who would appear for it. The present rule rejects that position.

Wright & Miller, *Federal Practice and Procedure*, Vol. 8A, Ch. 6, § 2103 at 35 (1994) (emphasis added).

Rather than attempting to comply with the Federal Rules as they currently exist, Wyeth would try to roll the clock back to before the Rule 30(b)(6) enactment, which allowed large corporations like Wyeth to create obstacles by forcing a party to guess which witnesses might have knowledge of a particular topic, each of which would then deflect the questions to a series of other witnesses not present, creating a shell game to thwart the opposing party. As further stated in Wright and Miller, such shell games continued, at least by one large drug company, after the 1970 amendments.[2]

Wyeth has more than ample resources to locate and designate the appropriate witnesses to facilitate this discovery. Wyeth is a large conglomerate which earned $20.4 billion in worldwide net revenue in 2006. Moreover, Wyeth has already gathered all of the information pertinent to these issues. In fact, Wyeth was prepared to go to trial

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[2] "Consider the remarks made by Judge Frank Theis regarding obstacles encountered by plaintiffs in Dalkon Shield litigation:

> The project manager for Dalkon Shield explains that a particular question should have gone to the medical department. The medical department representative explains that the question was really [in] the bailiwick of the quality control department. The quality control department representative explains that the project manager was the one with the authority to make a decision on that question. * * * [I]t is not at all unusual for the hard questions posed in Dalkon Shield cases to be unanswerable by anyone from Robins. Lord, The Dalkon Shield Litigation: Revised Annotated Reprimand by Chief Judge miles W. Lord, 1986, 9 Hamline L.Rev. 7,11."

Wright & Miller, *Federal Practice and Procedure*, Vol. 8A, Ch. 6, § 2103 at 35 (1994).

on these very issues in the *Teva* case, and thus already expended the resources to gather this information in litigating that case. Therefore, it should not be at all burdensome to Wyeth to provide Impax with access to this information through a 30(b)(6) deposition, let alone unduly so. Rather, it appears that Wyeth simply wishes Impax to laboriously and expensively prod through other discovery means to get to the same point.

Impax respectfully requests that this Court put an end to Wyeth's delay tactics and order Wyeth to produce 30(b)(6) witnesses on the eight general topics particularly described in Impax's Second Amended Notice within 30 days. Impax can complete this deposition in four days or less.

II. FACTUAL BACKGROUND

Because its Opposition Brief to Wyeth's Motion for Protective Order dated February 21, 2007 laid out much of the relevant discovery history of this case [*see* D.I. 90, at 3-4], Impax will not repeat it here. Instead, the background below explains how Impax's Second Amended Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6) is directed to the underlying facts of the case and the extent to which this information is within Wyeth's control.

A. Wyeth Filed This Patent Infringement Case Against Impax About One Year Ago

This lawsuit is approximately one year old, and only one deposition has been taken so far.

B. Impax's Notice Seeks Facts Within Wyeth's Corporate Knowledge

Impax's original 30(b)(6) Notice was served on November 20, 2006. After meet and confers, Impax narrowed its request and served an Amended Notice on January 22, 2007. Wyeth objected again. Although the Amended Notice listed focused relevant topics and described them with particularity, Wyeth objected to all but 5 topics and attempted to impose improper time period and/or scope limitations to 13 others.

Wyeth subsequently moved this Court for a protective order to strike the

Amended Notice and limit its scope. The Court granted Wyeth's motion without prejudice to Impax to re-notice the depositions. Declaration of Mary B. Matterer in Support Of Defendant Impax Laboratories, Inc.'s Motion to Compel Deposition Pursuant to Fed. R. Civ. P. 30(b)(6) ("Matterer Decl."), Ex. C at 14. The Court observed that the subjects described by Impax's counsel at the hearing seemed like fair discovery, but suggested that any further notice indicate the amount of time to be spent on each topic and the discoverable issues embraced by each topic. *Id.* at 14-15. In view of the advice provided by the Court at the March 2, 2007 hearing, counsel for Impax, including local counsel, spent a week revising Impax's Notice to comply with the Court's guidelines. On March 9, 2007, Impax served its Second Amended Notice, which sets forth 8 general topics directed to specific issues and calculated to yield substantive evidence for trial. Matterer Decl., Ex. B.

Impax's Second Amended Notice was served under cover letter which specifically informed Wyeth of Impax's best estimates of the time frames for each topic for a total deposition of about four days:

> Based on the information we have to date, we estimate the time-frame being broken down among the below eight (8) general topics as follows:
>
> I. WYETH'S ALLEGED CONCEPTION AND REDUCTION TO PRACTICE OF THE "INVENTIONS" IN THE PATENTS (3 hours)
>
> II. EVOLUTION OF WYETH'S COMMERCIAL PRODUCT -- DEVELOPMENT AND CHARACTERISTICS (4 hours)
>
> III. WYETH'S FAILURES OF OTHER EXTENDED RELEASE TECHNOLOGIES WITH VENLAFAXINE (4 hours)
>
> IV. OTHER EXTENDED RELEASE FORMULATIONS WHICH MIGHT INVALIDATE THE WYETH PATENTS OR RENDER THEM UNENFORCEABLE (4 hours)
>
> V. FACTS EVIDENCING INEQUITABLE CONDUCT BY MISCHARACTERIZING THE CLINICAL STUDIES ON NAUSEA AND FAILURE TO DISCLOSE HIGHLY MATERIAL INFORMATION (3 hours)

VI. FACTS SUPPORTING STATEMENTS IN THE PATENTS OR REQUIRED TO UNDERSTAND THEM; AND PATENT PROSECUTION PRACTICE AND RECORDKEEPING (3 hours)

VII. WYETH'S NEW DRUG APPLICATION (NDA) AND STATEMENTS MADE TO THE FDA THAT CONTRADICT THE PATENTS AND WYETH'S INTERPRETATION OF THE CLAIMS (3 hours)

VIII. THE ALLEGED COMMERCIAL SUCCESS BY WYETH IS NOT ATTRIBUTABLE TO THE ALLEGED INVENTION BUT TO ADVERTISING AND PROMOTION (4 hours)

> Obviously, some topics may require less time and some more. So the above estimate should not be considered a restriction as to the amount of time actually spent on any one topic or even groups of topics, because a deponent may provide testimony that requires additional time to explore a given topic or group of topics or may dispose of another topic quickly. *But the overall length should not go over four days.*

Matterer Decl., Ex. A at 1-2 (emphasis added).

Despite the particularity of the topics and reasonableness of the time frame, in a letter dated March 13, 2007, Wyeth objected again by simply recycling its previous hollow arguments. Matterer Decl., Ex. D. Impax now moves to compel deposition pursuant to its Second Amended Notice.

III. ARGUMENT

A. The Second Amended Notice's Topics Relate Directly To Specific Issues In The Case And Would Yield Relevant Substantive Evidence To Narrow The Issues For Trial

The topics in Impax's Second Amended Notice are carefully targeted to discrete, relevant subject areas and would yield substantive evidence to shorten the trial. Not only has Wyeth made these subject areas important to the outcome of the litigation, but all are based on facts *completely within Wyeth's control.* Thus, Impax is entitled to obtain the factual underpinning of these issues, raised by Wyeth, to adequately prepare for trial. As such, Impax's Second Amended Notice sets forth, in an organized fashion, specific topics addressed to each of these subject matters, *with time estimates as to each subject.* These topics directly focus discovery on the facts within Wyeth's possession – facts *on which Wyeth relies* in making its contentions. Under the general topic headings below

Impax addresses the relevance of each general topic and its importance to this case. The topic headings also reflect the estimated time for deposition of each topic.

Topic I **Wyeth's Alleged Conception And Reduction To Practice Of The "Inventions" In The Patents (Estimated Time: 3 Hours)**

The first general topic relates to the circumstances surrounding Wyeth's alleged conception and reduction to practice of the extended release formulations claimed in the patents-in-suit. Matterer Decl., Ex. B at 1. The dates of an invention's conception and reduction to practice are critical to a patent case because they determine the point in time before which certain events will invalidate the patent. *See, e.g., Mahurkar v. C.R.Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996) ("[s]ection 102(a) explicitly refers to invention dates, not filing dates. Thus, under section 102(a), a document is prior art only when published before the invention date"). Accordingly, Impax must explore the facts and circumstances of Wyeth's asserted dates and alleged diligence to fully challenge the validity of the patents-in-suit.

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The vehicle of a 30(b)(6) deposition is particularly appropriate here because there were many individuals at Wyeth involved in the development process over the years, and it is very difficult for Impax to determine exactly which roles were performed by whom.

Topic II **Evolution of Wyeth's Commercial Product – Development And Characteristics (Estimated Time: 4 Hours)**

The second noticed topic regarding the development and characteristics of the claimed extended release formulations bears on conception and reduction to practice, as discussed above, and further goes directly to the utility and operability of the claimed invention and the issue of whether the patents-in-suit adequately describe the claimed invention. Paragraph 4 of the Second Amended Notice addresses the development of certain critical features of the claimed invention. Matterer Decl., Ex. B at 2. Wyeth alleges that the patents-in-suit teach that a particular drug release profile achieves a particular result in human beings. Impax contends that not only has Wyeth failed to prove that the release profile achieves the particular result in human beings (e.g., no statistically significant improvement in the number of patients with nausea), but that the disclosure of one kind of extended release formulation is not sufficient to teach a person of ordinary skill in the art of pharmaceutical development and drug screening how to develop additional successful formulations by meeting the same profile. Thus, the inventors could not have possessed such a broad invention, and the patents would be invalid under 35 U.S.C. § 112, P 1. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation'") (citation omitted).

Again, this topic is appropriate for a 30(b)(6) notice because many individuals at Wyeth participated in the development and testing of the disputed drug profile, it is difficult for Impax to ascertain who did what over the years, and this information is within Wyeth's control.

Topic III **Wyeth's Failures Of Other Extended Release Technologies With Venlafaxine (Estimated Time: 4 Hours)**

As in any patent suit, validity of the patents and claim construction of the patents' claim terms is critical in this case. Impax's third noticed topic directly relates to interpretation of the patent claims and the validity of the patents. Wyeth asserts that the claims of the patents-in-suit are not limited to the specific MCC "extended release formulation" actually disclosed in the patents' specification, but instead should be broadly construed to cover additional extended release formulations. Matterer Decl. Ex. F at 19. One of the factual issues that informs the interpretation of this claim term is whether Wyeth achieved any success with other extended release formulations. The fact that Wyeth failed to achieve successful extended release formulations with other technologies, a fact which the patents' specification discloses, is compelling evidence that the term "extended release formulation" in the patent claims means only the specific formulation disclosed in the patents.

Indeed, Judge Martini's well-written Markman Opinion [Matterer Decl., Ex. G] on page 10 emphasizes the importance of failure evidence in supporting his narrow claim construction.[3]

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[3] The court's decision states as follows:

> Further, the specification distinguishes the "extended release formulations" of the invention from extended release hydrogel tablet formulations. Wyeth admits that under its proposed construction, an extended relase hydrogel tablet having the claimed *in vivo* characteristics may fall within the asserted claims. (See Wyeth's Br. At 16 n.6). *The specification, however, discloses that the inventors' attempts to develop extended release hydrogel tablets were "fruitless" and teaches one of ordinary skill that it is "impossible to achieve" the desired dissolution rates using hydrogel tablet technology.* Col. 4, lines 60-64; col. 10, lines 53-57. These statements were made without qualification. Accordingly, the specification supports construing "extended release formulation" more narrowly that Wyeth proposes. See *Cutlor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Claims are

(Footnote continued)

On the other hand, if this claim term were to be interpreted more broadly, then the claims would be invalid for lack of written description and invalid as anticipated by the prior art. Impax is entitled to fully explore Wyeth's failed attempts to develop extended release drug formulations because of its relevance to the claim construction and validity analyses. Paragraphs 5-8 of Impax's Second Amended Notice focus on this issue [Matterer Decl., Ex. B at 2-3], and it is appropriate for a 30(b)(6) deposition because of the long time frame of experimentation with these additional extended release technologies and the number of individuals involved.

Topic IV **Other Extended Release Formulations Which Might Invalidate The Wyeth Patents Or Render Them Unenforceable (Estimated Time: 4 Hours)**

Impax's fourth noticed topic pertains to pertinent prior art to the patents-in-suit.

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Impax contends that if "extended release formulation" is broadly interpreted, then the Alza patent and its venlafaxine extended release formulation is prior art that renders the patents-in-suit invalid as anticipated because it discloses, either expressly or inherently, each element of the asserted claims of the patents-in-suit. *See Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005) ("[a] single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation") (internal citation omitted). Paragraphs 9 and 10 of the Second Amended Notice are directed to features of the Alza prior art. Matterer Decl., Ex. B at 3-4. This topic is particularly well-suited for discovery by 30(b)(6) deposition at this time because Wyeth and Alza collaborated on an extended release formulation of venlafaxine using Alza's technology, and Wyeth has fought Impax's attempts to obtain discovery by other means on this subject.[4]

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not correctly construed to cover what was expressly disclaimed.") (emphasis added).

[4] Impax has engaged in a lengthy struggle to obtain discovery pertaining to the Alza product development through various means, and Wyeth has impermissibly resisted.

(Footnote continued)

Paragraph 11 focuses on additional prior art involving the drug propanolol [Matterer Decl., Ex. B at 4], which is relevant to the validity of the patents-in-suit. U.S. Patent No. 4,138,475 is prior art to the patents-in-suit and teaches a nearly identical extended release formulation with propanolol as the active ingredient instead of venlafaxine. Matterer Decl., Ex. H. During prosecution of the patents-in-suit, Wyeth amended its patent claims to overcome a Patent Office rejection for obviousness based on this propanolol patent. Matterer Decl., Ex. I. Moreover, Wyeth had a propanolol extended release formulation on the market at the time the initial provisional application for the patents-in-suit was filed. As such, comparisons between propanolol and venlafaxine are known to Wyeth and are directly pertinent to understanding the scope and validity of the claimed invention.

Topic V **Facts Evidencing Inequitable Conduct By Mischaracterizing The Clinical Studies On Nausea And Failure To Disclose Highly Material Information (Estimated Time: 3 Hours)**

In this case, Impax asserts that the patents-in-suit are unenforceable due to Wyeth's inequitable conduct during the patent application process. Specifically, Wyeth falsely told the Patent Office that three clinical studies showed a statistically significant reduction in the incidence of nausea. These studies were used to convince the Patent Office to grant the patents. Moreover, Wyeth intentionally withheld the Cunningham article, which demonstrated the true results of the studies: that both Effexor® IR and Effexor® XR made the same number of patients nauseous. Accordingly, Impax's fifth noticed topic relates to two articles reporting on the incidence of nausea in the clinical studies at issue and the factual underpinnings of the drug effects Wyeth claims in the

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Wyeth refused to respond to Impax's interrogatory on this issue, and Impax had to turn to the Court for relief. *See* D.I. 76, 88 and 93. Although this Court granted Impax's motion to compel a response to this interrogatory, [Matterer Decl., Ex. C], Wyeth has still not answered this interrogatory (No. 35). Finally, Impax tried to obtain the relevant documents from the Alza Corporation itself, but Wyeth has delayed their production by dragging their feet on the protective order.

patents-in-suit. Matterer Decl., Ex. B at 4-6. Because the duty of candor to the Patent Office extends to the inventors and others involved in the patent application process, this topic focuses directly and with particularity on who had knowledge of the articles and the pertinent data. *See Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348, 1351 n.3 (Fed. Cir. 2005) ("[i]n the context of an inequitable conduct determination, the 'applicant' includes anyone under a duty to disclose material information to the PTO pursuant to 37 C.F.R. section 1.56, namely: the inventor, the prosecuting attorney or agent, and anyone associated with the inventor or the assignee who is substantively involved in the preparation or prosecution of the application"). Impax's discovery efforts so far have revealed some awareness and knowledge on Wyeth's part of the subject matters of these topics. Impax now seeks to discover the full extent of Wyeth's knowledge, (who, what, where and when), which may involve numerous individuals with a duty of candor to the Patent Office.

Topic VI **Facts Supporting Statements In The Patents Or Required To Understand Them; And Patent Prosecution Practice And Recordkeeping (Estimated Time: 3 Hours)**

Impax's sixth noticed topic is also highly relevant to its inequitable conduct defense and to claim construction. This general topic relates to statements in the patents and Wyeth's patent prosecution practice. Matterer Decl., Ex. B at 6-7. Paragraphs 18-21 address important, discrete statements, examples and tables from the patents' specification. *Id.* at 6. As discussed above, the proper interpretation of the claim terms and the utility and written description for the claims depends on the statements in the specification and the accuracy of the data disclosed. Accordingly, Paragraphs 18 and 19 of the Second Amended Notice relate to facts supporting the underlying data and experimental records of the examples and tables in the patents' specification. *Id.* Paragraphs 21 and 22 each address a specific statement in the specification and in the patents' prosecution history that Impax contends are misleading. *Id.* Paragraphs 23 and 24 pertain to Wyeth's patent application practice and document retention procedures,

which will assist in resolving the inequitable conduct issues by shedding light on where and under whose control key documents would be located. *Id.* at 7.

The remaining subtopic under this general topic, addressed in Paragraph 25, seeks the factual bases for Wyeth's assertions regarding one specific and critical misleading statement in the patents' specification. Matterer Decl., Ex. B at 7. In particular, the specification states that Wyeth's claimed extended release formulation "showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." Matterer Decl., Ex. J at column 2, lines 52-55. A person having ordinary skill in the art of clinical trials would read this statement to mean that each of the three studies showed the stated improvement. In its Reply to Impax's Amended Answer, Wyeth denied representing to the Patent Office that each clinical study established a statistically significant improvement of extended release formulation over the conventional tablets. D.I. 46 at 6, ¶ 19. Wyeth further contends that it had combined or "pooled" the data from the three studies at the time the patent application containing this statement was filed in the Patent Office. *Id.* at 6, ¶ 20. Thus, the facts surrounding these assertions go to the root of Impax's inequitable conduct argument because they would help to prove that Wyeth possessed the intent to mislead the Patent Office.

Topic VII **Wyeth's New Drug Application (NDA) And Statements Made To The FDA That Contradict The Patents And Wyeth's Interpretation Of The Claims (Estimated Time: 3 Hours)**

The seventh general topic is Wyeth's New Drug Application for the claimed extended release formulation and statements Wyeth made to the FDA that contradict portions of the specification and its asserted interpretation of the claims. Wyeth's communications (or lack thereof as to certain claimed features like the incidence of nausea) to the FDA, and the timing of those communications, are highly relevant to the priority dates of the claims. As discussed above, Wyeth's conception and reduction to practice dates inform the validity analysis of the patents-in-suit. The substance of certain

communications to the FDA also bears on the inequitable conduct analysis because contradictory statements to the FDA and the Patent Office could evidence an intent to mislead the Patent Office. *See, e.g., Bruno Indep. Living Aids v. Acorn Mobility Serv.*, 394 F.3d 1348, 1351 (Fed. Cir. 2005) (upholding a finding of inequitable conduct where the attorney prosecuting the patent withheld prior art from the Patent Office that the patentee concurrently disclosed to the FDA during the patent application process). Therefore, paragraph 26 of Impax's Second Amended Notice targets a few documents and studies Wyeth submitted to the FDA and seeks the facts underlying the statements and data presented therein. Matterer Decl., Ex. B at 8.

Topic VIII **The Alleged Commercial Success By Wyeth Is Not Attributable To The Alleged Invention But To Advertising And Promotion (Estimated Time: 4 Hours)**

Impax contends that the patents-in-suit are invalid because certain prior art references render the claims obvious. Wyeth counters that the alleged commercial success of its Effexor® XR product, especially relative to its initial immediate release venlafaxine compound sold under the name Effexor®, proves that the claimed extended release formulation is not obvious over the prior art. The critical issue in the commercial success analysis is whether the alleged commercial success of Effexor® XR is attributable to the claimed features of the invention or to unclaimed features and/or advertising campaigns. *See Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("[a] nexus between commercial success and the claimed features is required"). Impax maintains that any alleged commercial success is due to advertising and promotional messages and unclaimed features of the drug, particularly features of the compound itself that is sold as Effexor®. Thus, testimony concerning advertising budgets, rebate strategies, sales projections and profit margins, advertising content and market research for both Effexor® and Effexor® XR is all highly relevant to the alleged commercial success of the claimed inventions. In addition, because Wyeth is preparing to release a new anti-depressant related to Effexor® XR –

i.e., desvenlafaxine succinate – Wyeth's devised strategies to transition the market to its new drug likely address Effexor® XR's selling strengths and weaknesses and may establish whether its sales are due to promotional efforts or the claimed features of the invention. Accordingly, paragraphs 27-32 seek this relevant information [Matterer Decl., Ex. B at 8-9], and a 30(b)(6) deposition is appropriate on this topic because only Wyeth, not Impax, is in a position to determine which individual(s) at Wyeth is most knowledgeable about Effexor® XR marketing and profitability.

B. Impax's Notice Is Not Overbroad In View Of The Factors Set Forth In Rule 26

In responding to Impax's Second Amended Notice, Wyeth still objects as to many topics (topic nos. 1-11, 16-17 and 20-32) as overbroad and therefore unduly burdensome. Matterer Decl., Ex. D at 3. As recognized by Wyeth, Rule 26 sets forth the factors to determine whether a discovery request is *unduly* burdensome:

> Rule 26(b)(2)(iii) provides five factors to help the Court determine whether the burden or expense of a discovery request is proportional to the needs of the case: . . . (A) the needs of the case, (B) the amount in controversy, (C) the parties' resources, (D) the importance of the issues at stake in the litigation, and (E) the importance of the proposed discovery in resolving the issues.

Hagemeyer N. Am., Inc. v. Gateway Data Sci. Corp., 222 F.R.D. 594, 600 (E.D. Wis. 2004) (internal quotation of Rule 26(b)(2)(iii) omitted). In past briefing and in its latest objections, Wyeth has failed to address these relevant factors. Regardless, Impax addresses them here:

1. The "Needs Of The Case" Support Using The Most Efficient Discovery Method To Flesh Out The Supporting Facts And Narrow The Issues

As discussed in detail above, this deposition is needed to discover several key facts which underly critical issues in this case, including conception and reduction to practice of the claimed invention, prosecution of, and statements in, the patents-in-suit, knowledge of and facts underlying the pertinent prior art and clinical studies, statements to the Patent Office and the FDA, and knowledge of marketing and promotion of the

Effexor® and Effexor® XR products. A deposition pursuant to Fed. R. Civ. P. 30(b)(6) is particularly important in view of Wyeth's delays and obfuscation of discovery by other means.

Furthermore, this deposition is the most efficient way to proceed with discovery on these issues. The deposition transcripts for Wyeth's fact witnesses in the *Teva* litigation demonstrate that the persons who appeared to be participants in several key factual issues, such as (A) the development of Effexor® XR, (B) the conception and reduction to practice of the claimed invention of the patents-in-suit, (C) the prosecution of the patents-in-suit and (D) the prior art extended release formulation work by Wyeth *were unable to recall (or were not sufficiently prepared so as to recall) basic information on these subjects, much less key details.*[5] Thus, it would be pointless and inefficient for Impax to depose these individuals in this case. The most efficient way to proceed is for Wyeth, who knows which individuals possess the pertinent information, to designate those individuals pursuant to Impax's Second Amended Notice.

2. The "Amount In Controversy" Is Billions Of Dollars

The amount in controversy in the instant case is in the billions of dollars. Wyeth claims that Effexor® XR, is "one of the world's most commercially successful drugs." Indeed, the total sales for Effexor® XR in the U.S. in 2005 exceeded $2 billion. Therefore, this case is too important to prevent full discovery of critical issues.

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3. The "Parties' Resources" Are One-Sided In Favor Of Wyeth

As discussed above, Wyeth has more than ample resources to locate and designate the appropriate witnesses to facilitate this discovery, and indeed, Wyeth has already gathered all of the information pertinent to these issues. Wyeth was prepared to go to trial on these very issues in the *Teva* case, and thus already expended the resources to gather this information in litigating that case. Therefore, it should not be at all burdensome to Wyeth to provide Impax with access to this information through a 30(b)(6) deposition, let alone unduly so.

4. The "Importance Of The Issues At Stake In The Litigation And The Importance Of The Proposed Discovery In Resolving And Narrowing The Issues"

As discussed in detail above, efficient resolution of critical issues in this case depends on Impax's ability to take this deposition on these focused topics. These include conception and reduction to practice of the claimed invention, which is critical to the validity analysis of the patents-in-suit. The prosecution of the patents, and the facts underlying the statements in the patents are important to several crucial issues, including claim construction, validity, inequitable conduct and enablement. The inequitable conduct issues also may turn on Wyeth's knowledge of the pertinent prior art and clinical studies and some of the factual issues surrounding them. As explained above, Wyeth's statements to the Patent Office and the FDA are very pertinent to enablement and inequitable conduct issues. Finally, information on Wyeth's marketing and promotion of the Effexor® and Effexor® XR products is essential to resolve the issue of commercial success.

C. Wyeth's Other Objections As To Privilege And Contention Interrogatories Are Weak Restatements Of Previous Arguments

Wyeth continues to object to many topics claiming that they delve into areas that touch on privileged subject matter (topic nos. 1-2, 12, 14 and 20-25), and are akin to contention discovery (topic nos. 1, 9, 12, 14, 16-17, 20-22 and 25-26). The parties have

fully briefed these issues, and Impax will not restate them here. *See* D.I. 82, 90 and 97. Sufficed to say, when these same topics were last raised, the Court found some of these specific topics to be "fair discovery," directly contrary to Wyeth's position. Matterer Decl., Ex. C at 15. Although the Court expressed no concern in these regards, Impax is prepared to address them at a hearing on this motion, if needed.

IV. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court grant its motion to compel Wyeth's deposition on the topics set forth in Impax's Second Amended Notice.

Dated: March 16, 2007

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